UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,596	02/15/2002	Alan D. Snow	017170-0010-999	2850

20583 7590 04/02/2008

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
CHONG, YONG SOO	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
04/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/077,596	SNOW ET AL.	
	Examiner	Art Unit	
	YONG S. CHONG	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-38,55 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-38,55 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/15/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/17/2007 has been entered.

Claim(s) 1-27, 39-54 have been cancelled. Claim(s) 28-38, 55-56 are pending. Claim(s) 28, 36-38, 55 have been amended. Claim(s) 28-38, 55-56 are examined herein.

Applicant's amendments have rendered the 112 rejection of the last Office Action moot, therefore hereby withdrawn.

Applicant's arguments have been fully considered but found not persuasive. The 103(a) rejections of the last Office Action are maintained for reasons of record and modified below as a result of the new claim amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 28-38, and 55-56 are rejected under 35 U.S.C. 103(a) as being obvious over Kuznicki et al. (5,681,569 of record).

Kuznicki et al. discloses a composition comprising green tea solids extracted from tea material, i.e., 0.01-0.35% flavanols or catechins wherein the catechin or a mixture of two or more the catechins are catechin, epicatechin, gallocatechin, epigallocatechin gallate and epicatechin gallate (see particularly col.3 lines 20-21 and 26-28), and a pharmaceutical carrier (i.e., water). See also abstract, co1.2, lines12-14; Example I, II, and III at co1.10, and claims 1 and 5-6. Thus, the green tea composition of Kuznicki et al. inherently comprises proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin herein.

The inherency of the green tea compositions containing proanthocyanidins and/or procyanidins is supported by the references by Hashimoto et al. (see "FC" in PTO-1449 submitted April 30, 2004). Hashimoto et al. teach that proanthocyanidins are isolated from oolong tea (a well known green tea), and/or the flesh leaves of green teas therein, wherein proanthocyanidins can be degraded to catechin and epicatechins by

hydrolysis. Most importantly the compounds identified by Hashimoto et al. in the qreen tea compositions are the instant compounds havinq the formula I or II (see Chart 2, the first two compounds on the top of paqe 3257). Morimoto et al. also teach that proanthocyanidins or procyanidins wherein proanthocyanidins can be degraded to catechins and epicatechins.

Kuznicki et al. also discloses the composition therein is therapeutically useful in improving cognitive performance (see col.3 line 33 in particular). The therapeutic effective amount of a catechin or mixture of catechins, within the instant claim (10-100mg/kg of bodyweight of the subject), is disclosed in the Example I and III (see col. 10 lines 1-41) as shown in the calculation below:

Example III discloses that a person can consume 835 cc (835 ml) of a beverage prepared according to Example I (see col.10 lines 40-41).

Since the water in the composition in Example I is 94.45%, the composition is aqueous solution. The density of water = 1 g/ml, thus the total amount of the composition in Example I is 835 g.

According to Example I, the effective amount of catechins (or flavanols)

= 835g X 0.097% (see co1.10 line 15 in particular) = 0.8099 g = 809.9 mg

OR in different calculation, according to Example I (see particularly at col.10 lines 6 and 13-14)

the effective amount of catechins

= 835g X 0.35/100 X 29/100 = 0.8475 g = 847.5 mg.

Since a standard person weight is 70 kg, the range of effective amounts of catechins is 10 mg/kg X 70 kg =700 mg to 1000 mg/kg X 70 kg = 70,000 mg.

Thus, the effective amount of catechins as exemplified in Example I in the composition of Kuznicki et al., 809.9 mg or 847.5 mg, is within the instant claimed range.

Kuznicki et al. also discloses that catechins therein are extracted from green teas or other plants, and isolated from green tea by methods well known to those in the art (see particularly at col.4 lines 6-14). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, which is an inherent property of the composition of Kuznicki et al. Kuznicki et al. also discloses that catechins can be prepared by synthetic chemical method or commercially available (see col.4 lines 14-17).

However, Kuznicki et al. does not specifically disclose a pharmaceutical composition consisting essentially of a therapeutically effective amount of a proanthocyanidin of formula I or II.

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made to have optimized the amount of the active agent so as to formulate a pharmaceutical composition consisting essentially of a therapeutically effective amount of a proanthocyanidin of formula I or II.

A person of ordinary skill in the art would have been motivated to formulate a pharmaceutical composition consisting essentially of a therapeutically effective amount of a proanthocyanidin of formula I or II because: (1) a proanthocyanidin of formula I or II

is taught as an active agent is disclosed in the composition and (2) it is obvious to optimize the amount when the general conditions are given. Therefore, one would have had a reasonable expectation of success in formulating a pharmaceutical composition consisting essentially of proanthocyanidin of formula I or II.

Generally, mere optimization of ranges will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimal or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also *In re Peterson*, 315 F. 3d at 1330, 65 USPQ 2d at 1382 "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." MPEP 2114.04.

.

Claim(s) 28, 31-38, and 55-56 are rejected under 35 U.S.C. 103(a) as being obvious over JP 10245342 of record.

JP 10245342 discloses a pharmaceutical composition for diminishing the toxicity in nerve cells caused by β-amyloid protein comprising a catechin or two or more of catechin such as epigallocatechin gallate and epicatechin gallate prescribed in effective amounts (doses) of diminishing the toxicity of β -amyloid protein (see particularly page 1, the 2nd paragraph; claims 1-3 at page 1; page 2 [0001], [0002]), and a pharmaceutical carrier (i.e., water). See also page 7 [0028]; page 8 [0029]. Thus, the

green tea composition in JP 10245342 inherently comprises proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin herein since catechins are known to encompass these compounds which are known to be isolated from green tea, as discussed above based on the references by Hashimoto et al., and Morimoto et al.

JP 10245342 also discloses that catechins therein are extracted from teas or other plants, and isolated and purified by HPLC (see page 6 [0027]). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, and substantially pure isolated, which is an inherent property of the composition therein.

However, JP 10245342 does not specifically disclose a pharmaceutical composition consisting essentially of a therapeutically effective amount of a proanthocyanidin of formula I or II.

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made to have optimized the amount of the active agent so as to formulate a pharmaceutical composition consisting essentially of a therapeutically effective amount of a proanthocyanidin of formula I or II.

A person of ordinary skill in the art would have been motivated to formulate a pharmaceutical composition consisting essentially of a therapeutically effective amount of a proanthocyanidin of formula I or II because: (1) a proanthocyanidin of formula I or II is taught as an active agent is disclosed in the composition and (2) it is obvious to optimize the amount when the general conditions are given. Therefore, one would have

had a reasonable expectation of success in formulating a pharmaceutical composition consisting essentially of proanthocyanidin of formula I or II.

Claim(s) 28, 31-38, and 55-56 are rejected under 35 U.S.C. 103(a) as being obvious over Hashimoto et al. (of record in PTO-1449 submitted April 30, 2004).

Hashimoto et al. discloses a composition comprising a catechin or two or more of catechins such as epigallocatechin and dimers and proanthocyanidins (having the formula I and II herein) and/or procyanidins such as the dimers and trimers of catechin and epicatechin in effective amounts, and a pharmaceutical carrier (i.e., water). See abstract. Thus, the oolong tea composition in Hashimoto et al. comprises the instant compounds herein since these compounds are known to be isolated from oolong tea. Most importantly the compounds identified by Hashimoto et al. in the green tea compositions are the instant compounds having the formula I or II (see Chart 2, the first two compounds on the top of page 3257).

Hashimoto et al. also discloses that proanthocyanidins are extracted from teas or other plants, and isolated (see page 6 [0027]). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, and substantially pure isolated, which is an inherent property of the composition therein.

However, Hashimoto et al. does not specifically disclose a pharmaceutical composition consisting essentially of a therapeutically effective amount of a proanthocyanidin of formula I or II.

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made to have optimized the amount of the active agent so as to formulate a pharmaceutical composition consisting essentially of a therapeutically effective amount of a proanthocyanidin of formula I or II.

A person of ordinary skill in the art would have been motivated to formulate a pharmaceutical composition consisting essentially of a therapeutically effective amount of a proanthocyanidin of formula I or II because: (1) a proanthocyanidin of formula I or II is taught as an active agent is disclosed in the composition and (2) it is obvious to optimize the amount when the general conditions are given. Therefore, one would have had a reasonable expectation of success in formulating a pharmaceutical composition consisting essentially of proanthocyanidin of formula I or II.

Claim(s) 28, 31-38, and 55-56 are rejected under 35 U.S.C. 103(a) as being obvious over Morimoto et al. (PTO-892).

Morimoto et al. discloses a composition comprising a catechin or two or more of catechins such as epigallocatechin and dimers and procyanidins (having the formula I and II herein) such as the dimers and trimers of catechin and epicatechin in effective amounts, and a pharmaceutical carrier (i.e., water). See abstract, page 908-909. Most importantly the compounds identified by Morimoto et al. are the instant compounds havinq the formula I or II (see paqe 909, Compound 3 and paqe 908).

However, Morimoto et al. does not specifically disclose a pharmaceutical composition consisting essentially of a therapeutically effective amount of a proanthocyanidin of formula I or II.

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made to have optimized the amount of the active agent so as to formulate a pharmaceutical composition consisting essentially of a therapeutically effective amount of a proanthocyanidin of formula I or II.

A person of ordinary skill in the art would have been motivated to formulate a pharmaceutical composition consisting essentially of a therapeutically effective amount of a proanthocyanidin of formula I or II because: (1) a proanthocyanidin of formula I or II is taught as an active agent is disclosed in the composition and (2) it is obvious to optimize the amount when the general conditions are given. Therefore, one would have had a reasonable expectation of success in formulating a pharmaceutical composition consisting essentially of proanthocyanidin of formula I or II.

Claim(s) 28, 31-38, and 55-56 are rejected under 35 U.S.C. 103(a) as being obvious over Hatano et al. for reasons of record stated in the Office Action dated September 30, 2003.

Hatano et al. discloses a composition for anti-HIV comprising or inherently comprising a catechin or two or more of catechins such as epigallocatechin and dimers or proanthocyanidins oligomers having the formula I and II herein and/or procyanidins

such as the dimers and trimers of catechin and epicatechin in effective amounts, and a pharmaceutical carder (i.e., water). See abstract.

Thus, the composition in Hatano et al. inherently comprises the instant compounds herein since these compounds are known to be isolated from Camellia japonica plants. See abstract.

Hatano et al. also discloses that catechins therein are extracted from plants, and isolated (see page 6 [0027]). Thus, their percentage purity herein is known to significantly exceed a proportion percentage of the catechin presence in a plant, and substantially pure isolated, which is an inherent property of the composition therein.

However, Hatano et al. does not specifically disclose a pharmaceutical composition consisting essentially of a therapeutically effective amount of a proanthocyanidin of formula I or II.

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made to have optimized the amount of the active agent so as to formulate a pharmaceutical composition consisting essentially of a therapeutically effective amount of a proanthocyanidin of formula I or II.

A person of ordinary skill in the art would have been motivated to formulate a pharmaceutical composition consisting essentially of a therapeutically effective amount of a proanthocyanidin of formula I or II because: (1) a proanthocyanidin of formula I or II is taught as an active agent is disclosed in the composition and (2) it is obvious to optimize the amount when the general conditions are given. Therefore, one would have

had a reasonable expectation of success in formulating a pharmaceutical composition consisting essentially of proanthocyanidin of formula I or II.

Response to Arguments

Applicant argues that each of the cited prior art references do not teach or suggest to alter green tea extract to consist essentially of the proanthocyanidins of the instant claims. Applicant also argues that the other components of the green tea extracts materially affect the basic and novel characteristics of the tea. In particular, it is well known in the art that such other components have therapeutic activity.

This is not persuasive because Examiner views the limitation in the instant claims "consisting essentially of" as "comprising" or open transitional language since Applicant has not met the burden of stating the basic and novel characteristics of the claimed invention. How is one of ordinary skill in the art to know if certain components of the green tea extract would materially affect the basic and novel characteristics of tea when the basic and novel characteristic of the present invention is not disclosed? Applicant has not disclosed what the basic and novel characteristic of proanthocyanidin of the claimed invention. Nonetheless, it is Examiner's assertion that one cannot distinguish between the components of green tea extract in terms of any basic or novel characteristic that is present in any one component and not present in another since all of the components are known for same purpose or therapeutic activity.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S Chong/
Patent Examiner, Art Unit 1617

YSC

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617